

AMENDMENTS TO THE CLAIMS

1. (Original) a device for placement within a mammal at a position near the stomach for the treatment of obesity, said device comprising:

(a) at least two or more expandable devices; wherein said expandable devices are sized and shaped such that when expanded said expandable devices decrease the volume of the stomach;

(b) at least one or more filling tubes having an inlet and an outlet connected to each of said expandable devices such that fluid can flow through said filling tubes to inflate or deflate said expandable devices;

(c) an access device having an adjusting port connected to each of said filling tubes for deflating and inflating said expandable devices; wherein said access device is sized and shaped such that a tight seal is formed between said adjusting port and said filling tube, and wherein said access device is sized and shaped such that said access device may be placed subcutaneously near the antero-lateral abdominal wall of the mammal; and

wherein:

(d) when a fluid carrier containing fluid is attached to said adjusting port, fluid may be injected or withdrawn from said expandable devices; wherein as fluid is injected into said expandable devices, said expandable devices expand to decrease the volume of the stomach.

Claims 2-5. (Canceled)

6. (Original) A device as recited in Claim 1, wherein at least two of said expandable devices are spherical-shaped.

7. (Original) A device as recited in Claim 1, wherein at least one of said expandable devices is crescent-shaped.

8. (Original) A device as recited in Claim 1, wherein said device additionally comprises a subcutaneous anchor sized and shaped such that said subcutaneous anchor anchors said expandable devices to the antero-lateral abdominal wall of the mammal.

9. (Original) A device as recited in Claim 8, wherein said subcutaneous anchor is a distensible

balloon.

10. (Original) A device as recited in Claim 8, wherein said subcutaneous anchor is a ring lock.

11. (Canceled)

12. (Original) A device as recited in Claim 1, wherein said fluid is selected from the group consisting of CO₂, isotonic dextrose, and an isotonic saline.

13. (Original) A device as recited in Claim 1, wherein said fluid carrier is a hypodermic syringe.

14. (Previously Presented) A device as recited in Claim 1, wherein said device additionally comprises one or more intragastric anchors sized and shaped such that said intragastric anchors are inserted into the stomach to bind said expandable devices against the exterior surface of the stomach body; wherein the number of said intragastric anchors corresponds to the number of said expandable devices.

15. (Previously Presented) A device as recited in Claim 14, wherein said filling tubes additionally comprise at least one intragastric access channel sized and shaped such that exterior and interior portions of the stomach may be accessed by said intragastric anchors.

16. (Original) A device as recited in Claim 14, wherein said intragastric anchors are collapsible, fixation discs.

Claims 17-30. (Canceled)

31. (Previously Presented) A device for placement within a mammal at a position near the stomach for treatment of obesity, said device comprising:

at least two expandable portions, wherein said expandable portions are sized and shaped such that when placed adjacent the stomach and expanded, said expandable portions form a barrier to reduce the volume of the stomach;

at least one filling tube having an inlet and an outlet, wherein each said expandable portion is connected to an outlet of at least one of said at least one filling tube so that fluid can flow through said at least one filling tube to inflate or deflate said expandable portions; and

an access device having a adjusting port connected to at least one of said at least one filling tube for deflating and inflating said expandable portions, wherein a tight seal is formed between said adjusting port and said at least one filling tube, and wherein said access device is sized and shaped such that said access device may be placed subcutaneously.

32. (Canceled)

33. (Currently Amended) The device of claim 31 ~~32~~, wherein a first of said at least two expandable portions ~~said first expandable portion~~ is at least partially inflated with a liquid and a second of said at least two expandable portions ~~said second expandable portion~~ is at least partially inflated with a gas.

34. (Canceled)

35. (Previously Presented) The device of claim 31, wherein at least one of said expandable portions is crescent-shaped.

36. (Canceled)

37. (Previously Presented) The device of claim 33, wherein said liquid is selected from the group consisting of isotonic dextrose and isotonic saline.

38. (Previously Presented) The device of claim 31, further comprising a subcutaneous anchor sized and shaped such that said subcutaneous anchor anchors said expandable portions to the antero-lateral abdominal wall of the mammal.

39. (Previously Presented) The device of claim 38, wherein said subcutaneous anchor comprises a balloon.

40. (Canceled)

41. (Previously Presented) The device of claim 38, wherein said subcutaneous anchor comprises a ring lock.

42. (Previously Presented) The device of claim 31, further comprising at least one intragastric anchor sized and shaped such that said intragastric anchors are insertable into the stomach to bind said expandable portions against an exterior surface of the stomach.

43. (Canceled)

44. (Previously Presented) The device of claim 42, wherein at least one of said filling tubes comprises at least one intragastric access channel sized and shaped such that exterior and interior portions of the stomach are accessible via said intragastric anchors.

45. (Previously Presented) The device of claim 42, wherein at least one of said at least one intragastric anchors is collapsible.

Claims 46-49. (Canceled)

50. (Previously Presented) The device of claim 42, wherein said at least one intragastric anchor is covered with a biocompatible material to help seal a gastric puncture site formed when anchoring said at least one intragastric anchor.

51. (Canceled)

52. (Previously Presented) The device of claim 31, wherein said at least two expandable portions are expandable to form a compressive barrier that reduces the volume of the stomach and minimizes post-implantation movement.

53. (Previously Presented) The device of claim 52, wherein a shape of said compressive barrier is adjustable, via changing the volume of one or more of said at least two expandable portions, to

complement a contour of surrounding tissues and organs.

54. (Canceled)

55. (Previously Presented) The device of claim 31, wherein at least one of said expandable members comprises polyurethane elastomer.

Claims 56-58. (Canceled)

59. (Currently Amended) The method of claim 106 ~~58~~, wherein said expanding comprises expanding the at least one expandable portion ~~portions~~ to a partially expanded configuration prior to said anchoring, and then at least one of the expandable portions is further expanded.

60. (Canceled)

61. (Canceled)

62. (Currently Amended) The method of claim 106 ~~58~~, wherein said anchoring comprises placing a subcutaneous anchor within a fatty layer between the skin and abdominal wall or subperitoneal region of the patient.

63. (Canceled)

64. (Currently Amended) The method of claim 104 ~~58~~, wherein the device is passed through the opening via an access sheath inserted in the opening.

65. (Currently Amended) The method of claim 64, wherein the ~~expandable~~ portions are contained within introducer tubes that are passed though the access sheath.

66. (Currently Amended) The method of claim 65, wherein the ~~expandable~~ portions are released from the introducer sheaths after said positioning.

67. (Currently Amended) The method of claim 104 58, wherein said positioning comprises positioning the ~~expandable~~ portions at a pregastric location.

68. (Currently Amended) The method of claim 104 58, wherein said positioning comprises positioning the ~~expandable~~ portions at a retrogastric location.

69. (Currently Amended) The method of claim 104 58, further comprising inserting a nasogastric tube into the stomach.

70. (Currently Amended) The method of claim 104 59, wherein upon ~~the~~ further expansion of at least one of the at least one expandable portions, a compressive barrier is formed that reduces the volume of the stomach and minimizes post-implantation movement.

71. (Currently Amended) The method of claim 106 58, wherein said anchoring comprises expanding a balloon-like device that circumscribes at least one filling tube connected to said expandable portions and protruding out of the abdominal wall.

72. (Currently Amended) The method of claim 106-58, wherein said anchoring comprises locking a ring lock around at least one filling tube and against the abdominal wall, said at least one filling tube being connected to said at least one expandable portion ~~portions~~ and protruding out of the abdominal wall.

73. (Canceled)

74. (Currently Amended) The method of claim 104 58, wherein said ~~minimally-invasive~~, percutaneous opening is made by inserting a ~~micropuncture~~ needle through an access site below the rib cage, into the peritoneal cavity immediately in front of the anterior gastric wall.

75. (Currently Amended) The method of claim 74, further comprising passing a wire ~~microwire~~ through the needle ~~microneedle~~ under fluoroscopic guidance, into the peritoneal cavity.

76. (Currently Amended) The method of claim 75, further comprising removing said ~~needle~~ ~~microneedle~~ over said ~~wire~~ ~~microwire~~ and inserting an introducer over said ~~wire~~ ~~microwire~~ through said percutaneous opening and into the peritoneal cavity.

77. (Canceled)

78. (Currently Amended) The method of claim ~~76~~ ~~77~~, further comprising progressively dilating the percutaneous opening with progressively larger dilators.

79. (Currently Amended) The method of claim 78, further comprising placing an ~~a peel-away~~ access sheath through the opening after said progressively dilating.

Claims 80-83. (Canceled)

84. (Currently Amended) The method of claim ~~79~~ ~~83~~, further comprising removing the ~~peel-away~~ access sheath and anchoring the ~~expandable~~ portions against the abdominal wall by placing an anchor subcutaneously between the skin and the abdominal wall.

85. (Canceled)

86. (Currently Amended) The method of claim ~~84~~ ~~85~~, further comprising cutting said at least one filling tube to an appropriate length for attachment to an access member and attaching said at least one filling tube to said access member, and placing said access member within the fatty layer between the skin and the abdominal wall.

87. (Canceled)

88. (Currently Amended) A method of treating obesity in a patient, said method comprising:
making a ~~minimally-invasive~~, percutaneous opening to the abdominal cavity of the patient;
sequentially passing at least two expandable portions of a device through said opening, while in a contracted configuration;
positioning the expandable portions adjacent the stomach of the patient;

expanding the expandable portions; and
anchoring the device to the abdominal wall of the patient.

89. (Previously Presented) The method of claim 88, further comprising anchoring said expandable portions to the stomach.

90. (Previously Presented) The method of claim 89, wherein said expandable portions are anchored to the stomach prior to anchoring the device to the abdominal wall.

91. (Currently Amended) The method of claim 89, wherein each expandable portion member includes a filling tube extending therethrough, each filling tube having two channels, said method further comprising anchoring at least one of the expandable portions to the stomach by installing an intragastric anchor through one of said channels.

92. (Currently Amended) The method of claim 91, further comprising puncturing the stomach wall with a needle; ~~injecting contrast medium into the stomach to determine the location of the needle relative to the stomach fluoroscopically;~~ and advancing the intragastric anchor in a collapsed configuration through the needle using a guidewire, wherein the anchor has a suture affixed thereto; wherein upon exiting the needle, the intragastric anchor expands to an expanded configuration that prevents it from being retracted back out of the stomach.

93. (Previously Presented) The method of claim 92, further comprising removing the needle and inserting the guidewire and suture through one of said channels.

94. (Previously Presented) The method of claim 92, further comprising removing the guidewire and pulling back on the suture to anchor the intragastric device to the stomach wall.

95. (Previously Presented) The method of claim 94, further comprising repeating the steps for intragastric anchoring for each remaining expandable portion that has not yet been anchored to the stomach.

Claims 96-103. (Canceled)

104. (Currently Amended) A method of treating obesity in a patient, said method comprising:
making a ~~minimally invasive~~, percutaneous opening through ~~to~~ the abdominal wall of the patient;
passing a device having at least two portions through ~~though~~ said opening;
positioning the at least two expandable portions adjacent the stomach ~~in an anatomical~~
~~compartment, space or layer of the abdominal wall~~ of the patient; and
expanding at least one of the portions to form a barrier that inhibits expansion of the stomach.

105. (Previously Presented) The method of claim 104, further comprising changing a shape of the barrier by increasing or decreasing expansion of at least one of the portions.

106. (Previously Presented) The method of claim 104, further comprising anchoring the device to the abdominal wall of the patient.

107. (New) A method of treating obesity in a patient, said method comprising:
making a percutaneous opening to the abdominal cavity of the patient;
passing an expandable device, while in a contracted configuration, through said opening;
positioning the expandable device adjacent the stomach of the patient;
expanding the expandable device; and
anchoring the expandable device, relative to at least one structure in the abdominal cavity.

108. (New) The method of claim 107, further comprising anchoring an adjustment member that is connected to the expandable member via a conduit, to a portion of the patient's body.

109. (New) The method of claim 107, wherein said positioning comprises positioning the expandable device anteriorly of the stomach to occupy a space normally occupied by the stomach.

110. (New) A method of treating obesity in a patient, said method comprising:
making a minimally invasive opening to the abdominal cavity of the patient;
passing an expandable device, while in a contracted configuration, through said opening;
positioning the expandable device adjacent the stomach of the patient;
anchoring the expandable device to at least one structure in the abdominal cavity; and

expanding the expandable device.

111. (New) The method of claim 110, wherein at least two locations on the expandable device are anchored to at least one structure in the abdominal cavity.

112. (New) A method of treating obesity in a patient, said method comprising:
making a percutaneous opening to the abdominal cavity of the patient;
passing an expandable device, while in a contracted configuration, through said opening;
positioning the expandable device adjacent the stomach of the patient;
expanding the expandable device to occupy a volume of space and substantially prevent the stomach from expanding into the volume of space; and
anchoring the expandable device to at least one structure in the abdominal cavity.

113. (New) A method of treating a patient, said method comprising the steps of :
passing a device including an expandable member having at least one trans-abdominally detectable marker into the body of the patient;
advancing the device into the abdominal cavity of the patient while tracking and guiding the advancing by trans-abdominally detecting the location of the at least one marker, relative to the patient's anatomy, as the device is advanced; and
anchoring at least a portion of the expandable member, relative to at least one structure in the abdominal cavity.

114. (New) The method of claim 113, further comprising expanding the expandable member to an expanded configuration in a space in the abdominal cavity to perform at least one of: prevention of expansion of the stomach of the patient into the space; and compression of a portion of the stomach.

115. (New) A method of treating a patient, said method comprising:
passing a device including an expandable member in a collapsed configuration through an opening in the skin of the patient, and into the abdominal cavity of the patient;
anchoring at least a portion of the expandable member, relative to at least one structure in the abdominal cavity without piercing the stomach; and
expanding the expandable member to an expanded configuration in a space in the abdominal

cavity to perform at least one of: prevention of expansion of the stomach of the patient into the space; and compression of a portion of the stomach.

116. (New). The method of claim 115, wherein said method is performed as a percutaneous procedure.

117. (New) The method of claim 115, wherein said method is performed as a laparoscopic procedure.

118. (New) The method of claim 115, wherein a guidewire is passed through the skin of the patient, and into the abdominal cavity, and wherein the device is passed over the guidewire to guide the device to an intended location in the abdominal cavity.

119. (New) The method of claim 115, further comprising inserting a sheath through a minimally invasive opening made through the skin and the abdominal wall, wherein the guidewire is inserted through the sheath to pass the guidewire through the skin and abdominal wall and into the abdominal cavity.

120. (New) The method of claim 115, wherein said device further comprises a second expandable member, said method further comprising at least partially expanding the second expandable member.

121. (New) The method of claim 115, wherein the device is passed in a compact configuration, the device being provided with looped tabs, the compact configuration being achieved by rolling the device to align opposite sets of the looped tabs, and inserting a rod or wire through the aligned sets of looped tabs.

122. (New) The method of claim 115, wherein the device is passed in a compact configuration, the compact configuration being achieved and maintained by compacting the expandable member and inserting the expandable member within a sheath.

123. (New) The method of claim 115, wherein the device is passed in a compact configuration

via an introducer that maintains the device in the compact configuration during said passing, said method further comprising opening splittable jaws of the introducer, once the device has been placed in the space in the abdominal cavity.

124. (New) The method of claim 123, wherein said anchoring is performed after said opening.

125. (New) A device to compress the stomach from the outside comprising: a first non-expanded configuration and a second expanded configuration wherein said device is adapted to be placed in between the peritoneum and the anterior wall of the stomach and wherein said device is configured to create stomach restriction when in its final position and when in its expanded configuration.

126. (New) The device of claim 125, wherein said device is adapted and sized to fit through a percutaneous conduit.

127. (New) The device of claim 125, wherein said device is further adapted to attach to the abdominal wall.

128. (New) The device of claim 125, wherein said device is further adapted to attach to the abdominal wall with a fastener.

129. (New) The device of claim 125, wherein said device is adapted to slide over a flexible connector to reach said final position.

130. (New) The device of claim 125, wherein said device is adapted to attach to the anterior wall of the stomach or a surrounding structure using a suture; and, wherein said device is adapted to slide over the suture.

131. (New) The device of claim 125, wherein said device is inflatable.

132. (New) The device of claim 125, wherein said device in said expanded configuration substantially covers the external surface of the stomach.

133. (New) The device of claim 125, wherein said device further comprises an attached anchor.

134. (New) The device of claim 125, further comprising an adjustable component wherein said adjustable component allows for different levels of expansion depending on the amount of fluid within the adjustable component.

135. (New) The device of claim 1, wherein said device further comprises an attached mesh.

136. (New) A method of fastening a device to one wall of a gastrointestinal organ comprising:
passing said device through a patient's abdominal skin, wherein the device is in an undeployed configuration; passing an anchor through a patient's abdominal skin wherein said anchor is in an undeployed configuration;

deploying said device;

connecting said device and said anchor by a connector such that said anchor and device are fastened to a wall of said gastrointestinal organ by said connector, wherein said connector prevents said device and said anchor from moving apart; and

deploying said anchor to its deployed configuration;

wherein said device induces satiety in said patient.

137. (New) The method of claim 136, wherein said connector is a suture.

138. (New) The method of claim 136, wherein the gastrointestinal organ is the stomach, and said device is located outside the stomach.

139. (New) The method of claim 138, wherein said anchor is located at least partially inside the stomach, said device comprises an inflatable balloon and said connector is a suture.

140. (New) The method of claim 136, wherein said device comprises an inflatable balloon.

141. (New) The method of claim 136, wherein said anchor is covered with a mesh and said connector is a suture.

142. (New) The method of claim 136, wherein the gastrointestinal organ is the stomach, said device comprises an inflatable balloon, and said anchor is located outside of the stomach.

143. (New) The method of claim 142, wherein said device is located outside of the stomach.

144. (New) The method of claim 136, wherein the gastrointestinal organ is the stomach, said device is located outside of the stomach, said connector is a suture and said anchor is covered with a mesh.

145. (New) A method of treating an obese patient comprising:
penetrating through the abdominal wall of a patient with a balloon adapted to track over a connector, wherein the balloon is expandable from a first undeployed configuration to a second deployed configuration, and wherein the balloon is fixed to a least two points inside the abdomen and wherein the balloon is further contoured to maintain contact with the gastrointestinal organ.

146. (New) A method of placing a device to restrict flow of food in to the stomach of a patient comprising:
penetrating the abdominal wall of a patient;
contacting the stomach of the patient with a connector;
pushing an extragastric balloon through the abdominal wall while the extragastric balloon is in contact with the connector and while the extragastric balloon is undeployed and thence contacting the stomach of the patient with the balloon; and
fixing the extragastric balloon to an outer portion of the stomach.

147. (New) The method of claim 146, further comprising cutting the connector so that the residual of the connector remains in the abdominal cavity.

148. (New) The method of claim 146, further comprising cutting the connector so that the residual of the connector traverses at least a part of the abdominal wall.

149. (New) The method of claim 148, further comprising attaching an access port to the

connector operable to inflate or deflate the extragastric balloon.

150. (New) The method of claim 146, further comprising visualizing the connector under fluoroscopy.

151. (New) The method of claim 146 wherein said method is performed laparoscopically.